

Exhibit 11

FILE PRODUCED NATIVELY

A New Low Profile Nitinol — ePTFE Flexible Double Disc Occlusion Device

Neil Wilson—Royal Hospital for Sick Children, Glasgow, Scotland, UK • Larry A. Latson—The Cleveland Clinic Foundation, Cleveland, OH • Evan Zahn—Miami Children's Hospital, Miami, FL

Abstract

A double disc nitinol framed expanded polytetrafluoroethylene (ePTFE) device has undergone evaluation for transcatheter closure of atrial septal defect (ASD). Mechanized in vitro testing of frame strength and flexibility demonstrated excellent performance. In vivo testing of the device in a canine model showed excellent results. The device was found to be safe and effective in the treatment of ASDs. The device was found to be safe and effective in the treatment of ASDs. The device was found to be safe and effective in the treatment of ASDs.

Fourteen implantations were performed in dogs with surgically created ASDs of approximately 10-12 mm diameter. Seven devices were implanted acutely to assess the delivery system and retrievability. Seven devices were deployed for chronic 90 day biocompatibility without incident. In the seven acute implantations, the device was found to be safe and effective in the treatment of ASDs. The device was found to be safe and effective in the treatment of ASDs. The device was found to be safe and effective in the treatment of ASDs.

The GORE occlusion device demonstrates excellent structural integrity and biocompatibility. Its flat profile and flexibility minimize tissue trauma and facilitate easy repositioning and removability. Ongoing chronic animal studies with a range of device sizes will further early human studies.

Computerized Finite Element Analysis

Finite element analysis is a computer simulation where the stress and strain of a material under load is calculated. This is accomplished by analysing the strain encountered by each of the small segments depicted in the diagram. The colour coding indicates the areas of maximal strain (red). Maximum strain was found in the central portion of the device. The device was found to be safe and effective in the treatment of ASDs. The device was found to be safe and effective in the treatment of ASDs. The device was found to be safe and effective in the treatment of ASDs.

Biocompatible Materials



The GORE SDCD consists of a single length of Nitinol wire with an attached ePTFE membrane. The membrane is made of a single length of Nitinol wire with an attached ePTFE membrane. The membrane is made of a single length of Nitinol wire with an attached ePTFE membrane. The membrane is made of a single length of Nitinol wire with an attached ePTFE membrane. The membrane is made of a single length of Nitinol wire with an attached ePTFE membrane.

GORE Septal Defect Closure Device (SDCD)



SDCD Shortly After Deployment in Canine Model of ASD

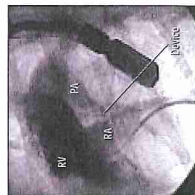


The device is round and very flexible to maximise the possibility of low trauma. Flexibility of the central portion allows excellent positioning of the device prior to release. The circumferential wire frame makes disengagement of the device extremely unlikely even with device to defect ratios of 1.5 to 1.

Safety Features

The SDCD is specifically designed with a high priority on safety and retrievability of the device. The device turns itself around so the catheter is always in the center of the device. The device is fully deployed, the device can be simply withdrawn back into the catheter as long as the mandrel remains attached. After position changes, the cord allows for removal of the device at the time of mandated detachment and lock release.

Right Atrial Angiogram Demonstrating No Right to Left Shunt



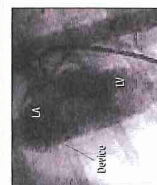
Right atrial angiogram shows excellent apposition of the device to the septum. There is no right to left shunt. There is no angiographic evidence of right to left shunting. Transoesophageal echocardiography also confirmed no right to left shunting by contrast echo.

Device Deployment

The left atrial side of the device has been deployed and has assumed its circular shape. The device is being pulled against the left atrial side of the atrial septum. As demonstrated in the photograph to the left, the device is very resistant to pulling through the ASD.



Left Atrial Contrast Injection Shows No Left to Right Shunt



Contrast has been injected through a catheter in the left atrium inserted through the left atrial appendage. Filling of the left atrium and left ventricle is apparent. No left to right shunt is seen. Transoesophageal echocardiography with echo contrast injection in the left atrium.

Acute Deployment of SDCD



Photographs of the left and right atrial sides of a SDCD deployed approximately 30 minutes prior to sacrifice. Note the flat profile and excellent apposition of the device to the atrial septal surface (15 mm device in 10 mm ASD).

SDCD 90 Days After Implantation



By 90 days after deployment, there is excellent tissue covering of the device. The Nitinol frame can be seen through the tissue. The device is not exposed to the vessel lumen. The device is not exposed to the vessel lumen. The device is not exposed to the vessel lumen. The device is not exposed to the vessel lumen.

90 Day Histology, 25 mm SDCD



The ASD created via thoracotomy using a 1.25 cm punch. The defects were allowed to heal for approximately 21 days before device placement. The 25 mm diameter devices were found to be too large for the atrium of the 20-25 kg canine model. The large crista terminals in the model held the devices away from the septum preventing contact. The device was found to be safe and effective in the treatment of ASDs. The device was found to be safe and effective in the treatment of ASDs. The device was found to be safe and effective in the treatment of ASDs.